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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,773	09/03/1999	SILKE HEIN	MOBT:136	3052

7590

05/03/2002

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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 05/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/380,773

Applicant(s)

HEIN ET AL.

Examiner

Yong Pak

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-61 and 64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-61 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on February 22, 2002, canceling claims 1-37 and 62-63, amending claims 38, 50 and 52-56 and adding claim 64, has been entered.

Claims 38-61 and 64 are pending.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

Response to Amendment

Claim Rejections - 35 USC § 112

Claims 52-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 52-56 contain new matter because the specification as originally filed contains no description or teachings of a genetically cell expressing the heterologous proteins recited in claims 52-56. Applicant is required to cancel the new matter in the reply to this Office Action.

withdrawn

Response to Arguments

Applicant's arguments filed February 22, 2002 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

Claims 38-61 and 64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that both the specification and art teaches a wide variety of PHA synthase genes from numerous organism and a wide variety of fatty acid acyl-CoA transferase gene from numerous sources and thereby satisfies the written description requirement. The examiner disagrees. While a variety of the two enzymes are described in the specification and in the art, the claim encompasses a method of using a genus of PHA synthase and a genus of fatty acid acyl-coenzyme A transferase from any source and with any structure.

Claims 38-61 and 64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preparing a polyester using PHA synthase gene of SEQ ID NO:1 and a 4-HB Co-A transferase gene of SEQ ID NO:2, does not reasonably provide enablement for a method of preparing a polyester using a PHA synthase gene and 4-HB Co-A transferase gene different from SEQ ID NO:1 and 2, respectively. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the examples in the present specification together with the teachings of the two enzymes are sufficient for one skilled in the art to practice the invention. The examiner disagrees.

While a variety of the two enzymes are described in the specification and in the art, the claim encompasses a method of using a genus of PHA synthase and a genus of fatty acid acyl-coenzyme A transferase from any source and with any structure. The specification lacks guidance for a method using PHA synthase or fatty acid acyl-coenzyme A transferase from any source. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

Claim Rejections - 35 USC § 102

Claims 38-42, 44-61 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Dennis et al.

Applicants argue that the reference of Dennis et al. does not disclose the claimed process because there is no disclosure of genetically engineering an organism to express a fatty acid:acyl CoA transferase and that acetyl-CoA:4-hydroxybutyrate CoA transferase is not part of a "succinic semialdehyde metabolic pathway" because the enzyme by itself cannot produce succinic semialdehyde. The examiner disagrees.

Dennis et al. does teach a method of preparing polyesters using a cell comprising at least one recombinant sequence that encodes a PHA pathway and at least one recombinant sequence that encodes a succinic semialdehyde metabolic

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pathway (Column 3, lines 26-44) and teaches that an *Alcaligenes eutrophus* phaC polyhydroxyalkanoic acid synthase gene and a *Clostridium kluyveri* orfZ 4-hydroxybutyric acid acyl-coenzyme A transferase gene can be used as one of the sequences in addition to other genes (Figure 1, Column 6, line 4 through Column 7 line 18 and Column 8, line 63 through Column 9, line 39). Dennis et al. also teach that the *Clostridium kluyveri* orfZ 4-hydroxybutyric acid acyl-coenzyme A transferase gene is one of the genes of the succinyl-CoA metabolic pathway and can be used in conjunction with the other gene (Column 9, lines 20-39).

Regarding claims 50-56, Dennis et al. do teach a cell that is capable of producing the recited proteins and a culture medium that contains molecular oxygen. Regarding newly submitted claim 64, Dennis et al. teach a method for separating the polyester from the cells (Column 24, lines 50-62). Therefore, the teachings of Dennis et al. anticipates claims 38-42, 44-61 and 64.

Claim Rejections - 35 USC § 103

Claims 38-39 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dennis et al. in view of Greener et al.

Applicants argue that there is no motivation or suggestion to combine the teachings of Dennis et al. and Greener et al. because there is no reasonable expectation of success and that high transformation efficiency does not necessarily result in an increased production of enzymes. The examiner disagrees. One of ordinary skill in the art would have had a reasonable expectation of success since transforming

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XL1-Blue cells is routinely performed in the art resulting in an increased production of enzymes.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned

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are 703-872-9310 for regular communications and 703-746-7240 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

May 1, 2002


PONNATHAPU ACHUTHAMURTHY
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